REMARKS

The present application is directed to particulate vaccine compositions. These compositions are particularly useful for mucosal administration of vaccines especially by intra-nasal routes.

Applicants have amended Claims 1, 4, 6, 7, 8 and 26. Claims 2, 5 and 11 have been cancelled. Claims 27-32 have been newly added. Claims 14-25 are withdrawn from consideration as being drawn to a non-elected invention. Accordingly, Claims 1, 3-4, 6-10, 12-13, and 26-32 are pending and under consideration upon entry of this amendment.

In the Office communication mailed January 25, 2005, the Examiner refused to enter the amendment filed with the Request for Continued Examination on October 24, 2004 on the basis that an amendment changing the nature of an invention from a composition to a method was improper when filed with a Request for Continued Examination. Therefore, applicants have amended the claims in this Amendment to recite composition claims.

Rejections under 35 U.S.C. §112, second paragraph

Claim 4 has been amended to correct a typographical error. The term "the said adjuvant" now reads "the adjuvant". Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. §102

Claims 1-9 and 11-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Duncan *et al.* (WO 94/20070 published September 15, 1994, "Duncan"). Applicants respectfully traverse the rejection.

Duncan discloses vaccine compositions using polymeric mucoadhesives to deliver an antigen. Adjuvants are optionally included in the composition. Duncan does not disclose using **particulate** vaccines with the claimed adjuvants.

Claim 1 has been amended to recite a vaccine composition comprising pharmaceutically acceptable **particles**. The only reference to particulate vaccines in Duncan is in the background section of the patent on page 2. Duncan describes how in the past, antigens incorporated into microparticles, nanoparticles or liposomes may be more immunogenic than free antigens, and speculates that this was because they may be trapped in the mucous. Duncan discloses that **instead** of using particles, one could utilize mucoadhesives. This is clear, for example from the disclosure on page 14, lines 14-18, which stresses that the compositions should be simple combinations of immunogens, mucoadhesive and adjuvant. The remainder of the disclosure, including that which the Examiner describes on pages 9-10 should be read in that light.

Claims 1-13 have been rejected under 35 U.S.C. §102(e) as being anticipated by Griffin, K.F. *et al.* 1998 (*Vaccine* 16(5):517-521, "Griffin"). Applicants respectfully traverse the rejection.

The Examiner appears to be asserting that the poly(L)lactide disclosed in Griffin is an adjuvant. Claim 1 of the present application specifically lists different classes of adjuvants denoted A) to H). Applicants respectfully submit that poly(L)lactide is not encompassed in the classes of adjuvants listed in the claims of the present application and poly(L)lactide is not positively charged as recited in class C). Therefore, this polymer does not fall within the definitions of any of classes A) to H) of Claim 1.

Similarly, the "second adjuvant" which the Examiner refers to as being disclosed in Griffin *et al.* is not encompassed by the claims of the present application. IFN-γ does not fall within any of the adjuvant classes (A) to (H) in Claim 1. Griffin does not describe any component which could be within the claimed classes of adjuvants (A) to (H) and therefore does not anticipate the present claims.

Claims 1-13 have been rejected under 35 U.S.C. §102(e) as being anticipated by Park *et al.* (United States Patent No. 6,267,987 B1 published July 31, 2001, "Park"). Applicants respectfully traverse the rejection.

Park discloses certain block co-polymers for use as carriers for pharmaceuticals. However Park simply suggests that these polymers are an "all purpose" carrier for an enormous range of drugs or other therapeutic agents. No adjuvant or immunostimulant properties are disclosed in this reference. Similarly, the block co-polymers described in Park fail to fall within the classes of adjuvants A) to H) listed in the claims. Furthermore, the complexes described by Park appear to form complexes with the molecules they are carrying, as illustrated in Figures 1 to 4 of the reference, but do not have a defined microcapsule or liposome structure as recited by the claims.

The properties illustrated in the present specification clearly show that the novel adjuvants have unexpected advantages when used in combination with specific immunogens in vaccines. This is not disclosed or taught in any way by Park. Therefore, Park does not anticipate the claimed composition.

Claim Objections

Claim 4 has been objected to because of an informality where the claim contains the typographical error "the said adjuvant". As mentioned above, applicants have amended Claim 4 to read "the adjuvant" and respectfully request withdrawal of this objection.

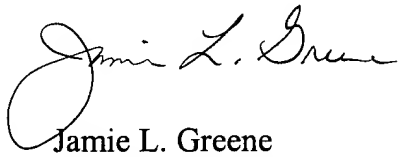
CONCLUSION

Applicants respectfully submit that this is a complete response to the Office Action dated January 25, 2005, and that the pending claims are in condition for allowance. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes any informalities remain in the application that can be resolved by telephone interview, a telephone call to the undersigned attorney is earnestly solicited.

Allowance of the claims is respectfully solicited.

Respectfully submitted,



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